



8/Declaration  
File No. A34293-PCT-USA (072944.0139) 1.132

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Choi et al.  
Serial No. : 09/831,929 Examiner : L. Channavajjala  
Filed : June 29, 2001 Group Art Unit : 1615  
For : BIOCIDAL COMPOSITION AND STERILIZATION METHOD  
USING THE SAME

DECLARATION UNDER 37 C.F.R. § 1.132

RECEIVED

SEP 27 2002

Hon. Assistant Commissioner for Patents  
Washington, DC 20231

TECH CENTER 1600/2900

Sir:

I, KI-SEUNG CHOI, hereby declare as follows:

1. I am a co-inventor of the invention disclosed and claimed in the above-captioned U.S. patent application.
2. I am an employee of SK Chemicals Co., Ltd., which is the assignee of the rights, title and interest in the United States of the invention disclosed and claimed in the above-captioned U.S. patent application.
3. I am a named inventor or co-inventor of several inventions disclosed and claimed in United States patents and patent applications.

4. I have reviewed the Official Action mailed May 21, 2002 by the U.S. Patent and Trademark Office for the above-captioned patent application together with U.S. Patent No. 5,278,178 to Hsu (hereinafter referred to as "Hsu"), Soviet Union Patent No. 1687261 (hereinafter referred to as "SU '261"), and Japanese Patent No. 10175809 (hereinafter referred to as "JP '809"), all of which were discussed therein.

5. Hsu discloses antimicrobial and biocidal compositions comprising an isothiazolone and one or more commercial biocides for control of microorganisms in various industrial systems. Hsu does not disclose the biocide composition of the present patent application where the composition comprises 3-isothiazolone and polyhexamethyleneguanidine phosphate.

6. SU '261 discloses the use of polyhexamethyleneguanidine gluconate as an active component in a disinfecting composition.

7. Claims 2-6 now pending in our patent application require the use of polyhexamethyleneguanidine phosphate in conjunction with 3-isothiazolone to make up the biocide composition and sterilization method we are disclosing in the present application.

8. The difference between the antibiotic abilities of polyhexamethyleneguanidine phosphate and the antibiotic abilities of polyhexamethyleneguanidine gluconate reflects a fundamental difference between the disclosure of SU '261 and the invention claimed in our patent application. The difference in the antibiotic abilities of each of these compounds can be determined by showing the

difference between the minimum inhibitory concentration (MIC) of polyhexamethyleneguanidine phosphate necessary for inhibiting certain microorganisms and the MIC of polyhexamethyleneguanidine gluconate necessary for inhibiting the same microorganisms.

9. Under my direction and control, the following experiments were conducted. The antibiotic abilities of polyhexamethyleneguanidine phosphate and polyhexamethyleneguanidine gluconate were compared by determining the minimum inhibitory concentration (MIC) in parts per million of each compound necessary to inhibit the growth of various microorganisms. These experiments were conducted in the same manner described in the Examples section of the present patent application, beginning at page 7, line 7 of the specification and continuing through page 9, line 17. Generally, the MIC of each of these two compounds was determined by visually observing with the naked eye the growth of microorganisms on the basis of "muddiness" of the solution.

10. When testing was performed to compare the antibiotic abilities of polyhexamethyleneguanidine phosphate and polyhexamethyleneguanidine gluconate, the results were as follows:

Table A

Microorganism Type	MIC (in ppm) Using Polyhexamethyleneguanidine Phosphate (Claim 6)	MIC (in ppm) Using Polyhexamethyleneguanidine Gluconate (SU '261)
<i>E. coli</i>	16	128
<i>K. pneumonia</i>	32	512
<i>P. vulgaris</i>	16	256

11. As seen in Table A above, when polyhexamethyleneguanidine phosphate (in accordance with the present invention) was used, the MIC required to inhibit growth of each microorganism tested was significantly lower than the MIC required to inhibit growth of the same microorganisms when polyhexamethyleneguanidine gluconate (disclosed by SU '261) was used. These results show that the antibiotic ability of polyhexamethyleneguanidine phosphate is surprisingly and unexpectedly greater than the antibiotic ability of polyhexamethyleneguanidine gluconate.

12. JP '809 discloses a bactericidal composition for industrial use where polyhexamethylenebiguanidine hydrochloride is included as one of the active ingredients.

13. The difference between the antibiotic abilities of polyhexamethyleneguanidine phosphate and the antibiotic abilities of polyhexamethylenebiguanidine hydrochloride reflects a fundamental difference between the disclosure of JP '809 and the invention claimed in our patent application. The difference in the antibiotic abilities of each of these compounds can be determined by showing the difference between the minimum inhibitory concentration (MIC) of polyhexamethyleneguanidine phosphate necessary for inhibiting certain microorganisms and the MIC of polyhexamethylenebiguanidine hydrochloride necessary for inhibiting the same microorganisms.

14. Under my direction and control, experiments similar to those described in Paragraph 9 above were carried out in order to compare the antibiotic abilities of polyhexamethyleneguanidine phosphate with the antibiotic abilities of polyhexamethylenebiguanidine hydrochloride. The MIC values (in parts per million) necessary to inhibit the formation of six different strains or microorganisms were determined for both polyhexamethyleneguanidine phosphate and polyhexamethylenebiguanidine hydrochloride. The following results were obtained:

**Table B**

<b>Microorganism Type</b>	<b>MIC (in ppm) Using Polyhexamethyleneguanidine Phosphate (Claim 6)</b>	<b>MIC (in ppm) Using Polyhexamethylene Biguanidine Hydrochloride (JP '809)</b>
<i>B. subtilis</i>	8	64
<i>S. aureus</i>	32	64
<i>P. aeruginosa</i>	64	32
<i>E. coli</i>	16	16
<i>K. pneumonia</i>	32	32
<i>P. vulgaris</i>	16	128

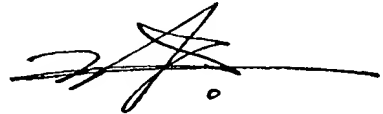
15. As seen in Table B above, when polyhexamethyleneguanidine phosphate (in accordance with the present invention) was used, the MIC required to inhibit growth of each microorganism tested was significantly lower than the MIC required to inhibit growth of the same microorganisms when polyhexamethylenebiguanidine hydrochloride (disclosed by JP '809) was used. These results show that the antibiotic ability of polyhexamethyleneguanidine phosphate is

surprisingly and unexpectedly greater than the antibiotic ability of  
polyhexamethylenebiguanidine hydrochloride.

16. I hereby declare that all statements made herein of my own  
knowledge are true and that all statements made on information and belief are believed to  
be true, and further that these statements were made with the knowledge that willful false  
statements and the like so made are punishable by fine or imprisonment, or both, under  
Section 1001 of Title 18 of the United States Code, and that such willful false statements  
may jeopardize the validity of any patent issuing from the above-captioned patent  
application.

September 19, 2002

Date



\_\_\_\_\_  
KI-SEUNG CHOI